IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	**Redacted - Public Version** C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Counterclaim- Defendants.*	**JURY TRIAL DEMANDED** [redacted]

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. NATURE AND STAGE OF PROCEEDINGS AND SUMMARY OF ARGUMENT

Moderna's COVID-19 vaccine helped end the pandemic and transformed Moderna from an obscure biotechnology company to a household name. Neither of those outcomes would have been possible without Moderna's use of key enabling technology concerning the delivery of nucleic acids like mRNA into cells, which Plaintiffs developed over many years and claimed in the patents asserted in this case. Moderna knowingly used the patented technology for years, openly, before shifting more recently to deny it publicly. Moderna even tried to invalidate Plaintiffs' patents in *inter partes* review proceedings before the USPTO and Court of Appeals for the Federal Circuit. After that effort largely failed, Moderna presented a host of new and recycled excuses in this suit. Plaintiffs request summary judgment as to three of those defenses: (1) nonobviousness; (2) enablement; and (3) derivation.[1]

With respect to the first issue, the law forecloses Moderna's attempted mulligan for its obviousness arguments. The PTO's Patent Trial and Appeal Board ("PTAB") already rejected Moderna's challenges to two of the Lipid Composition Patents (U.S. Patents 8,058,069 and 9,364,435). *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, 2019 Pat. App. LEXIS 13612, at *1 (P.T.A.B. Sept. 11, 2019) ("*'435 FWD*"). Section 315(e) of the Patent Act thereby plainly estops Moderna from asserting obviousness on any ground it raised or reasonably could have raised to the PTAB. Moderna nevertheless asserts obviousness of the '435 patent, ostensibly because the Federal Circuit left the PTAB's final written decision intact by dismissing Moderna's appeal rather than affirming on the merits. *ModernaTx, Inc. v. Arbutus Biopharma Corp.,* 18 F.4th 1352 (Fed. Cir. 2021) ("*'435 Decision*"). But the statute explicitly provides that it is the PTAB's final written decision—not appellate affirmance—that triggers estoppel. 35 U.S.C. § 315(e)(2).

[1] Plaintiffs will move for summary judgment on Moderna's § 1498 defense and indefiniteness in their Response, per Chief Judge Goldberg's Order. D.I. 485 ¶ 4.

Additionally, Moderna's obviousness defenses against all the Lipid Composition Patents depend on assertions that the Federal Circuit rejected squarely in affirming the '069 patent's validity. *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364 (Fed. Cir. 2021) ("*'069 Decision*"). That decision has preclusive effect and forecloses Moderna's arguments.

With respect to the second issue, Moderna's experts' opinions on non-enablement depend on improperly adding to the asserted claims various functional properties like potency and stability that the claims do not recite or require, or otherwise advancing arguments that, even if true, do not create a triable issue as a matter of law.

With respect to the third issue, Moderna contends that Plaintiffs derived the inventions claimed in the '651 patent from a Moderna patent application filed in 2012, a decade after the '651 patent's 2002 priority date and years after Plaintiffs first made the mRNA-lipid particles with the claimed high levels of full encapsulation. As a matter of law and logic, Moderna cannot establish that Plaintiffs "derived" the invention from Moderna's later-filed application.

II. BACKGROUND

The inventions described and claimed in the Asserted Patents tackled the most challenging problem that had vexed researchers for decades: how to deliver nucleic acid (such as DNA or mRNA) to cells, where it can exert its desired effect, without first being degraded by enzymes in the blood and rendered ineffective. As one Nobel Laureate explained it succinctly, the challenge with nucleic acid therapies was "delivery, delivery, delivery." Ex 19 (Check 2003) at -162.[2]

There are four Asserted Patents. Three are part of the "Lipid Composition Family": U.S. Patents 8,492,359, 9,364,435, and 11,141,378, which all share the same specification and inventors. That family also includes U.S. Patents 8,058,069 and 8,822,668, which Plaintiffs are

[2] Exhibit citations refer to the exhibits to the July 25, 2025 Declaration of Matthew W. Lachman. All emphases herein are added. A Person of Ordinary Skill in the Art is abbreviated as "POSA."

no longer asserting pursuant to the Court's Order regarding narrowing (D.I. 475). These Lipid Composition Patents claim novel nucleic acid-lipid nanoparticles ("LNPs") that are particularly well suited to protect and deliver nucleic acid, such as the mRNA in Moderna's vaccine, to their intended cellular targets. Without LNPs, the mRNA would degrade rapidly in the body, and the vaccine would be ineffective. These particles are comprised of nucleic acid and specified lipid components: (1) a "cationic" lipid, which exhibits a positive charge under certain conditions; (2) one or two "non-cationic" lipids, such as a phospholipid or cholesterol; and (3) a "conjugated" lipid, such as a "PEG"-lipid, that inhibits aggregation of particles. Ex 20 (Mitchell) ¶ 76. The novel ratio of the lipids—recited in the claims as a mole[3] percent (mol %) of the total lipid in the particle—affects the properties of the LNPs.

The patent in the second family, U.S. Patent No. 9,504,651, claims a formulation of lipid vesicles with certain lipid components and high levels of fully encapsulated mRNA. The inventors were able to achieve these high levels of nucleic acid encapsulation—a measurement of how much of the nucleic acid is within (and thus protected by) the lipid vesicles—by using novel particle manufacturing methods, which the patent specification explains in detail. *See* '651 patent, Fig. 13, 15:19-56, 18:30-43. The '651 patent discloses and claims these advantageous lipid vesicle formulations wherein a certain percentage of the mRNA is fully encapsulated in the lipid vesicles.

Moderna has long been aware of, and knowingly used, the technology claimed in the Asserted Patents. In 2015, Moderna entered into the first of four sublicenses to the Asserted Patents. Exs 21-24 (Acuitas Sublicenses). Those four sublicenses were limited in scope to specific viruses that did not include COVID-19. But that did not stop Moderna from building its scientific platform on Plaintiffs' technology. Moderna used that technology, for years, [redacted]

[3] A mole ("mol") is a measure of the amount of a substance, based on the number of molecules.

[redacted] Ex 25 (Himansu Tr.) 200:15-201:20, 203:6-203:23. When subsequent litigation confirmed the limited scope of Moderna's sublicenses, Moderna did not enter into a license agreement for any additional viruses (like COVID-19). Ex 26 (Arbutus Feb. 22, 2018 Form 8-K) at 2. Instead, it tried to invalidate the patents, filing largely unsuccessful challenges to two of the Lipid Composition Patents with the PTAB. Publicly, Moderna claimed it had "stopped using" Plaintiffs' LNP technology. *Id.* at 4. But that was not accurate. For example, in the preprint version of a journal article released in June 2020, Moderna admitted to using a lipid molar ratio claimed by Plaintiffs in its COVID-19 vaccine—but then edited references to the specific molar ratio out of the final publication. *Compare* Ex 27 (Corbett 2020 Preprint) at -729, *with* Ex 28 (Corbett 2020) at -506. That article explained that Moderna's "rapid response to the COVID-19 outbreak" was enabled by its use of "a fast, scalable, and safe mRNA/LNP vaccine platform"—that is, by using Plaintiffs' patented technology without permission and without obtaining a license. Ex 27 (Corbett 2020 Preprint) at -727. Moderna continued to use Plaintiffs' technology in its commercial vaccine, as evidenced by Moderna's own testing, including Certificates of Analysis submitted to FDA, as well as Plaintiffs' independent, unrebutted testing. Ex 20 (Mitchell) at ¶¶ 609, 611-615, 618, 621.

III. LEGAL STANDARD

Summary judgment is proper where, "drawing all reasonable inferences in favor of the nonmoving party, there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 147 n.15 (3d Cir. 2017). Because patents are presumed valid, the party challenging validity bears a clear and convincing burden to prove invalidity. *Massey v. Del Lab'ys, Inc.*, 118 F.3d 1568, 1573 (Fed. Cir. 1997). Summary judgment of validity thus does not require the movant to present any factual evidence. *Id.* Instead, Plaintiffs need only "show that [Moderna], who bears the burden of proof

at trial, failed to produce clear and convincing evidence on an essential element of a defense" of invalidity. *Eli Lilly & Co. v. Barr Lab'ys, Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

It is then up to Moderna to "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The non-moving party may not simply "rest upon mere allegation or denials of his pleading" but instead must "present affirmative evidence" sufficient "for a jury to return a verdict for that party." *Id.* at 249, 256-57. "Summary judgment is fully appropriate" where the "facts material to the decision are not in genuine dispute." *Avenal v. United States*, 100 F.3d 933, 936 (Fed. Cir. 1996).

IV. ARGUMENT

A. The Court Should Grant Summary Judgment of Nonobviousness of the Lipid Composition Patents

Moderna seeks to relitigate the outcome-determinative obviousness findings from its failed IPRs. Both statutory estoppel and issue preclusion prohibit it from doing so.

1. Moderna's Obviousness Arguments on the '435 Patent Are Estopped Under 35 U.S.C. § 315(e)(2)

35 U.S.C. § 315(e)(2) provides: a "petitioner in an [IPR] . . . *that results in a* ***final written decision*** . . . *may not assert* . . . in a civil action . . . that the claim is invalid *on any ground that the petitioner raised or reasonably could have raised* during that [IPR]." Moderna's IPR petition on the '435 patent "result[ed] in a final written decision." *'435 FWD*, 2019 Pat. App. LEXIS 13612. Thus, Moderna "may not assert" in this "civil action" "invalid[ity] on any ground that [it] raised or reasonably could have raised" in the IPR. § 315(e)(2). The statute therefore bars all of Moderna's obviousness arguments against the '435 patent. Moderna's sole argument is to rewrite § 315(e)(2) to include an exception to estoppel where an appeal from a final written decision is dismissed for lack of standing, but nothing in the statute supports Moderna's argument.

a. Moderna "Raised or Reasonably Could Have Raised" Its

Challenges to the '435 Patent in the IPR

The application of the plain statutory text is not in dispute. Moderna was the "petitioner in an [IPR]" challenging the '435 patent. *'435 FWD*, 2019 Pat. App. LEXIS 13612. That IPR "result[ed] in a final written decision under section 318(a)," § 315(e)(2), finding Moderna "has not shown by a preponderance of the evidence that" asserted claims 7, 8, 10, or 16 were unpatentable, *'435 FWD,* 2019 Pat. App. LEXIS 13612, at *1. Thus, by the statute's unmistakable terms, Moderna "may not assert . . . in a civil action" that any claim its petition challenged "is invalid on any ground that [it] raised or reasonably could have raised during" the IPR. § 315(e)(2).

The statutorily estopped arguments "that the petitioner 'reasonably could have raised' in its petition" are "invalidity grounds a skilled searcher conducting a diligent search reasonably could have been expected to discover." *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1298 (Fed. Cir. 2023). Every obviousness reference Moderna asserts against the '435 patent here is a reference that Moderna could have raised in the IPR. Ex 1 (Moderna Disclosures of Prior Art and Invalidity Defenses) at 4-5 (obviousness combinations). Moderna agrees, in no uncertain terms, that it is not "asserting that there are any prior art publications that could not have been found by a skilled searcher." Ex 2 (Sept. 19, 2023 Letter) at 9; Ex 3 (Moderna's Final Invalidity Contentions) at 66. Moderna does not dispute that it "reasonably could have raised" its obviousness grounds in its '435 patent IPR, mandating summary judgment. *Trs. of Columbia Univ. v. Symantec Corp.*, 390 F. Supp. 3d 665, 677 (E.D. Va. 2019).

b. Dismissal of Moderna's Appeal Is Irrelevant to § 315(e)(2)

The Federal Circuit dismissed the appeal from the PTAB decision because Moderna "failed to meet its burden" to show a case or controversy to establish standing. *'435 Decision*, 18 F.4th at 1362. Moderna now seeks to avoid estoppel on the basis of that dismissal. Ex 3 (Moderna's Final Invalidity Contentions) at 66. But the statute in no way conditions the applicability of

estoppel on the particulars of the adjudication on appeal, or any appeal at all.

"The controlling principle in this case is the basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written." *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 580 U.S. 405, 414 (2017). Here, § 315(e)(2) is clear: it triggers estoppel for an IPR "that results in a final written decision under § 318(a)." Period. *Intuitive Surg., Inc. v. Ethicon LLC*, 25 F.4th 1035, 1041 (Fed. Cir. 2022) ("[E]stoppel is triggered when an IPR proceeding results in a final written decision."). The statute provides no exception for final decisions that are appealed unsuccessfully due to lack of standing; whether a decision is appealed is irrelevant. Indeed, a court in this District has applied estoppel even where an appeal from a final decision is pending, reflecting the statute's clear language that the final decision, not the appeal or its particular disposition, triggers estoppel. *Trustid, Inc. v. Next Caller Inc.*, 2021 WL 3015280, at *1, *4 (D. Del. July 6, 2021) ("preventing Defendant from asserting prior art defenses . . . based on estoppel under § 315(e)(2)" during appeal); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 601 (D. Mass. 2018) (estopping party from reraising grounds it could not appeal). It cannot be the case that estoppel applies to prevent obviousness assertions before or during an appeal but no longer applies when an appeal is *unsuccessful* upon dismissal. Moderna's unprecedented exception should be rejected for the simple reason that it requires rewriting the statute.

The statutory context confirms the lack of Moderna's novel dismissed-appeal exception to § 315(e)(2). *See Star Athletica*, 580 U.S. at 414 (courts must "look to the provisions of the whole law"). The statute recites exceptions to § 315(e) estoppel, but dismissal of an appeal is not one of them. For example, § 317(a) provides that "no estoppel under section 315(e) shall attach" where the parties jointly terminate an IPR. "Where," as here, "Congress includes certain exceptions in a statute, the maxim *expressio unius est exclusio alterius* presumes that those are the only exceptions

Congress intended." *Ventas, Inc. v. United States*, 381 F.3d 1156, 1161 (Fed. Cir. 2004).

In support of its attempt to rewrite the statute, Moderna relies on *dictum* in *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1363 (Fed. Cir. 2019). Ex 3 (Moderna's Final Invalidity Contentions) at 66. There, the court addressed whether a petitioner's possibility of being estopped was sufficient to confer standing to appeal an IPR loss when it otherwise lacked an injury traceable to the patent. 923 F.3d at 1363. The court held that estoppel cannot confer standing. *Id.* In *dictum*, the court noted that, to adopt the Petitioner's clearly rejected position (that estoppel confers appellate standing), "we would also have to consider whether § 315(e) should be read to incorporate a traditional preclusion principle—that neither claim nor issue preclusion applies when appellate review of the decision with a potentially preclusive effect is unavailable." *Id.* But the court explicitly "decline[d]" to reach that issue, because it was unnecessary to the decision, and "[t]he parties have not briefed" it. *Id.* Nor has any other court ever held that a dismissed appeal somehow eliminates statutory estoppel: both before and after *AVX*, the Federal Circuit uniformly has held that estoppel does not confer standing *even if estoppel applied following a dismissed appeal*. Crucially, in doing so, the Federal Circuit assumed—in decision after decision—that estoppel still applies, even where a PTAB decision is not appealable due to lack of standing. *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1175-76 (Fed. Cir. 2017) ("estoppel provision[s] do[ ] not constitute an injury in fact"); *Consumer Watchdog v. Wis. Alumni Rsch. Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014); *JTEKT Corp. v. GKN Automotive Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018); *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374, 1378 (Fed. Cir. 2020); *Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1355 (Fed. Cir. 2019); *Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378, 1385 (Fed. Cir. 2021).

The statute's repeated departure from traditional preclusion principles illustrates the folly

of Moderna's argument. For example, § 315(e)(2) dispenses with the "identical issue" requirement, instead applying broadly to grounds the petitioner "raised" or "reasonably could have raised." Likewise, § 315(e)(2) is not limited to identical parties like claim preclusion, but instead estops the petitioner regardless of whether the patent owner was a party in both proceedings. Unsurprisingly, no court has interpreted § 315(e) contrary to its language to "incorporate a traditional preclusion principle—that neither claim nor issue preclusion applies when appellate review of the decision with a potentially preclusive effect is unavailable." *AVX*, 923 F.3d at 1363.

Indeed, the Federal Circuit, after its *dictum* in *AVX*, expressly rejected an attempt to import the "issue-preclusion rubric" into statutory "IPR estoppel." In *Click-to-Call Techs. LP v. Ingenio, Inc.*, 45 F.4th 1363, 1368 (Fed. Cir. 2022) ("*Click-to-Call II*"), the court held the "actually litigated" prong of issue preclusion does not apply to statutory estoppel, because the text's departure from traditional preclusion means "it would not be reasonable to engraft such a requirement into IPR estoppel." The same reasoning dooms Moderna's proposed exception.

The Federal Circuit has been consistent in declining to read common-law exceptions into the clear statutory language of § 315. In an earlier decision in the same case, *Click-to-Call Techs., LP v. Ingenio, Inc.*, 899 F.3d 1321 (Fed. Cir. 2018) ("*Click-to-Call I*"), *vacated on other grounds*, 810 F. App'x 881 (Fed. Cir. 2020), the court addressed § 315(b), which precludes IPR petitions "more than 1 year after" the "petitioner . . . is served with a complaint alleging infringement." The PTO interpreted the provision to embrace a common law principle that a complaint's dismissal without prejudice is treated "as though the action had never been brought," so that service of a later-dismissed complaint would not start the one-year clock. *Id.* at 1332-33. The Federal Circuit reversed: "where the statutory scheme is clear, we are not to 'invent an atextual explanation for Congress's drafting choices.'" *Id.* at 1335 (quoting *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 368

(2018)). "Served" meant "served," without atextual exceptions. So too here: "final written decision" means "final written decision," without Moderna's additional requirements.

c. Summary Judgment Is Proper

Moderna's references were raised or could have been raised in the IPR. The Court should enter summary judgment of nonobviousness on the '435 patent and estop Moderna from raising any challenge it raised or could have raised against it. *SiOnyx*, 330 F. Supp. 3d at 600.

2. Issue Preclusion Forecloses Moderna's Attempt to Relitigate Issues Decided by the Federal Circuit

In asserting obviousness of the Lipid Composition Patents, Moderna also seeks to relitigate the PTAB findings that the Federal Circuit affirmed in the non-dismissed '069 patent appeal. *'069 Decision*, 18 F.4th at 1376-77. As a matter of logic and law, Moderna's "inability to prove" obviousness "under the lower preponderance . . . standard at the PTAB" precludes it "from raising the argument under the higher clear and convincing evidence standard in district court." *SynQor, Inc. v. Vicor Corp.*, 2022 WL 6217132, at *17 (E.D. Tex. Sept. 26, 2022).

Courts consistently have held that agency decisions, like PTAB IPR decisions, trigger issue preclusion. *Papst Licensing GmbH v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250-51 (Fed. Cir. 2010); *B&B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S. 138, 148 (2015). Issue preclusion applies when (1) the same issue was previously adjudicated; (2) the issue was actually and finally decided; (3) the previous determination was necessary to the decision; and (4) the party being precluded was fully represented in the prior action. *Papst*, 924 F.3d at 1250-51; *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006). As set forth below, these elements are satisfied here, warranting summary judgment of nonobviousness.

a. Moderna Seeks to Relitigate the Same Issues

Though the '069 patent is no longer at issue, the asserted Lipid Composition Patents share

the same specification, and the obviousness analysis is materially the same for the asserted claims. The PTAB and Federal Circuit already rejected Moderna's obviousness arguments: (1) that it was "routine" to optimize the lipid components and amounts in LNPs based on the prior art, and (2) that the prior art taught a range of phospholipid that overlaps with the claimed ranges.

"Routine Optimization." The Lipid Composition Patents' claims recite nucleic acid-lipid particles comprising four lipid components: (1) a cationic lipid, (2) a conjugated lipid, and a non-cationic lipid including (3) cholesterol and (4) a phospholipid. *E.g.*, '435 patent, claim 7; *'069 Decision*, 18 F.4th at 1369. As relevant here, the claims recite ranges of the four lipids' molar ratios. Since the prior art does not disclose particles with the claimed molar ratio ranges (Moderna does not assert anticipation), Moderna argued before the PTAB and on appeal that it would have been routine for the POSA to optimize the lipid particle formulations in the prior art, which had different lipids and/or ratios, to arrive at the claimed ranges. *'069 Decision*, 18 F.4th at 1376 ("Moderna argues that . . . [prior art] presented a starting point that would have allowed a [POSA] to arrive at the claimed invention through routine optimization."). For example, because the prior art did not disclose a phospholipid range, Moderna argued that "the phospholipid range would have been obtainable through routine optimization using disclosed prior art formulations as starting points." *Id.* at 1369. Moderna specifically urged that routine optimization would use the prior art "2:40 [conjugated:cationic] formulation" as a "starting point[]," and that the POSA would "increase the amount of cationic lipid," among other changes "to each *individual* component." *Id.* at 1376. Moderna relied on the prior art '189 publication, which taught the 2:40 formulation, the '554 publication, and other references. *Id.* at 1368-69.

The PTAB and the Federal Circuit both rejected Moderna's obviousness theory decisively, finding that Moderna's routine optimization argument "failed to address the interdependence of

the claimed lipid components" and their "unpredictable interactivity." *Id.* at 1376-77. Yet Moderna seeks to relitigate this exact issue here, as illustrated below:

PTAB and Federal Circuit Findings	**Moderna's Arguments in this Case**
"[O]ptimizing the four interdependent lipid components in the prior art nucleic acid-lipid particles ***would not have been routine***" and concluding that there was "***unpredictable interactivity*** between the various lipid components." *'069 Decision*, 18 F.4th at 1377. "We are not persuaded by Petitioner's ***routine optimization*** argument at least as applied to the claimed phospholipid range." *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, 2020 WL 4237232, at *13 (P.T.A.B. July 23, 2020) ("*'069 FWD*"). [W]e ***are not persuaded*** that [Chen '554] teaches an overlapping phospholipid range such that the claims are *prima facie* obvious or that the adjustment of the phospholipid amount to within the claimed range would have been a matter of ***routine optimization***." *Id.* at *17.	"In my opinion, it would only take ***routine optimization*** for the POSA to arrive at the claimed molar ratios . . . ." Ex 4 (Anderson) ¶ 967. The POSA would identify the phospholipid range "in doing ***routine optimization*** of lipid molar ratios." *Id.* ¶ 823. "[U]sing ***routine optimization***, a POSA would have arrived at the claimed mole percent of phospholipid and cholesterol." *Id.* ¶ 619. "Using ***routine optimization***, a POSA would have arrived at the claimed mole percent of phospholipid." *Id.* ¶ 722.

There is no difference between Moderna's arguments here or the claims at issue that allows a second bite at the apple. Indeed, after Plaintiffs' expert, Dr. Niren Murthy, explained that Moderna's sole obviousness expert, Dr. Daniel Anderson, had advanced opinions "considered and rejected by the PTAB and/or the [Federal Circuit]," Ex 5 (Murthy) ¶ 260, Dr. Anderson, in his entire 169-page Reply Report, did not dispute that fact or identify a single difference between his "Routine Experimentation" or "optimization" theory and the "routine optimization" theory the PTAB and Federal Circuit rejected. *E.g.*, Ex 6 (Anderson Reply) ¶¶ 151, 243; § VIII.D. Instead, Dr. Anderson noted that he "cite[s] prior art" not addressed in the prior decisions and that the asserted claims are not identical to the '069 patent. *Id.* ¶ 134. Neither creates a new issue.

First, the prior art cited by Dr. Anderson that was not before the PTAB or Federal Circuit

is irrelevant to the issue preclusion analysis. As the Federal Circuit and this District have held repeatedly, a defendant's attempt to "buttress [its] case through different [prior art] evidence" does not create a new issue. *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1325 (Fed. Cir. 2003); *PureWick Corp. v. Sage Products, LLC*, 2023 WL 2734779, at *5 (D. Del. Mar. 31, 2023); *Sprint Comm'cns Co. v. Charter Comm'cns, Inc.*, 2021 WL 982726, at *9 (D. Del. Mar. 16, 2021); *see also Rudolph Techs., Inc. v. Camtek Ltd.*, 2016 WL 8668504, at *5 (D. Minn. Aug. 8, 2016) ("[I]ssue preclusion applies even if the underlying theory or evidence proffered in the second action is different."); Restatement (Second) of Judgments § 27 cmt. c, illus. 4. Although these cases involved challenges to the same patent(s) in both proceedings, the reasoning applies here. *See Papst*, 924 F.3d at 1249-50 (applying issue preclusion where patents differed between actions); *Amgen, Inc. v. Genetics Inst., Inc.*, 98 F.3d 1328, 1332 (Fed. Cir. 1996) (same). The Court should thus reject a "granular view" of issue preclusion and "decline[] to parse . . . obviousness further" based on Moderna's particular prior art. *PureWick*, 2023 WL 2734779, at *5.

Even were the particular references relevant, however, none of Moderna's disclosed prior art (Ex 1) presents an obviousness issue materially different from what the PTAB and Federal Circuit already decided. Dr. Anderson cites "Jadhav '218" but never asserts that it provides a substantively different teaching related to routine optimization, Ex 4 (Anderson) ¶¶ 824-825, 946-948, or that it somehow negates the prior finding that "the lipid components of the nucleic acid-lipid particle are interdependent" and "interact with each other unpredictably," foreclosing routine optimization. *'069 Decision*, 18 F.4th at 1374. On the contrary, Dr. Anderson did not dispute Dr. Murthy's opinion that the Jadhav '218 disclosure "is substantially similar if not identical" to the '554 publication the PTAB and Federal Circuit addressed. Ex 5 (Murthy), ¶ 300, Ex 6 (Anderson Reply) ¶¶ 35-36. Moderna cannot avert issue preclusion by citing a separate reference with

"substantially identical teachings with respect to" the relevant issues. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 763 F. Supp. 2d 671, 679-80 (D. Del. 2010).

Similarly, Dr. Anderson cites to purported teachings to use a lower amount of cholesterol to enhance "liposome recovery," Ex 4 (Anderson) ¶ 1005 (citing Semple 1996). But again, Dr. Anderson does not assert that this prior art teaches the claimed lipid ranges. It instead merely provides a different permutation of Moderna's already-litigated "general considerations to be taken into account with respect to each individual component" (in this case, the cholesterol component), which the Federal Circuit rejected as "fail[ing] to address the interdependence of the claimed lipid components and how adjustments would affect the nucleic acid-lipid particle as a whole," especially in view of the components' "unpredictable interactivity." *'069 Decision*, 18 F.4th at 1376-77. In other words, every change to an *individual* lipid concentration necessitates changes to the *other components*, because they sum to 100%, and the Federal Circuit found that the consequences of those changes are unpredictable and not routinely optimized. *Id.* Ignoring this finding, Moderna's approach again focuses myopically on individual lipid adjustments in isolation and fails to account for the "unpredictable" effect of those adjustments on the particle as a whole. *Id.* Moderna's argument thus fails for the same reasons as its prior rejected argument.

The same applies to Moderna's argument that a POSA would increase the "cationic lipid[] at the expense of phospholipid" to improve "encapsulation and transfection efficiency," Ex 4 (Anderson) ¶¶ 996-97 (citing Semple Article), as the court rejected Moderna's argument "to increase the amount of cationic lipid to increase transfection efficiency" as a basis for routine optimization. *'069 Decision*, 18 F.4th at 1376. Moderna again relies on the "2:40" formulation disclosed in the '189 publication and elsewhere, Ex 4 (Anderson) ¶ 618, yet the PTAB and Federal Circuit considered Moderna's same argument on this same formulation "as [a] starting point[] for

optimization" and found that it did not support achieving the claimed ranges through routine optimization. *'069 Decision*, 18 F.4th at 1376; *'069 FWD*, 2020 WL 4237232, at *15 (proposed "adjustments" to 2:40 formulation "hindsight driven" and not "routine optimization").

Second, there is no relevant difference between the Lipid Composition Patents' claims at issue here and the '069 patent's claims for issue preclusion purposes. Like the '069 patent claims the PTAB and Federal Circuit upheld, all but two asserted claims recite a range for the phospholipid component, in addition to requiring the same other three lipids. Though the numerical endpoints of certain of the lipid ranges differ between the asserted claims and the previously adjudicated claims, those distinctions are immaterial to Moderna's obviousness theory. Neither prior decision turned on the specific numerical endpoints, but rather on the "unpredictable interactivity between the" four recited lipid components, 18 F.4th at 1377—which are common to the '069 patent and the asserted claims—and the absence of *any* prior art teaching of a phospholipid range (discussed below), *id.* at 1374. And regardless, the "calculated" phospholipid range of "0-19.5 mol %" Moderna asserted (rejected in both decisions) overlaps with the asserted claims just like the '069 patent claims. *Id.* at 1375. Thus, because "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, [issue preclusion] applies." *Ohio Willow Wood Co. v. Alps South*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

The only distinction Dr. Anderson notes between the '069 claims and those at issue here is that the '378 patent claims "are not limited to any amount of cationic lipid." Ex 6 (Anderson Reply) ¶ 134. That distinction is immaterial as well: like the '069 patent, the '378 patent claims recite four lipid components and a particular range of phospholipid, and "the Board's finding that optimizing the four interdependent lipid components in the prior art nucleic acid-lipid particles would not have been routine" therefore is dispositive. *'069 Decision*, 18 F.4th at 1376-77.

"Overlapping Phospholipid Range." Along with rejecting Moderna's routine optimization theory for lipid ratios, the PTAB and Federal Circuit found that the prior art '189 and '554 publications do not teach a phospholipid range, so no "overlapping [phospholipid] range is actually taught by the prior art" and any "presumption of obviousness" did not apply. *'069 Decision*, 18 F.4th at 1373, 1375; *'069 FWD*, 2020 WL 4237232, at *12 ('189 does not "explicitly disclose[] a phospholipid range"); *id.* at *17 (same for '554); *see also '069 Decision*, 18 F.4th at 1374-75 (rejecting "premise that one could obtain a value for the amount of any one lipid component in the particle by adding up the amounts of the other three components and subtracting from 100%"). That preclusive finding forecloses Dr. Anderson's contrary argument that the prior art disclosed "Overlapping Ranges" giving rise to a "presumption of obviousness." *E.g.*, Ex 4 (Anderson) ¶¶ 972-991. Moderna's obviousness argument thus rests on the notion that a POSA could derive such a range through routine optimization. *E.g.* Ex 4 (Anderson) ¶ 823 ("To the extent [the '189] does not . . . disclose this claim element, it would be obvious in view of the knowledge of a POSA and/or obvious in combination with one or more of the prior art discussed below ***in doing routine optimization of lipid molar ratios***."). As discussed above, that is an improper effort to relitigate the PTAB's and Federal Circuit's findings.

* * *

Because Moderna's obviousness theories do not "materially alter the question of invalidity" decided by the PTAB and Federal Circuit, the issues are the "same" for purposes of issue preclusion. *Ohio Willow Wood*, 735 F.3d at 1342; *see Sprint*, 2021 WL 982726, at *9.

b. The Issues Were Actually and Finally Decided

The dispositive findings discussed above were "determined by a valid and final judgment" of the PTAB, affirmed by the Federal Circuit. *Jean Alexander*, 458 F.3d at 249. Plaintiffs and Moderna "vigorously litigated" obviousness in the IPR and the ensuing appeal. *Id.* at 254.

c. The Previous Determinations Were Necessary to the PTAB's and Federal Circuit's Decisions

In applying the "essential to the judgment" element, the governing Third Circuit holds "that independently sufficient alternative findings should be given preclusive effect." *Jean Alexander*, 458 F.3d at 255. The PTAB and Federal Circuit's nonobviousness conclusions are supported by the independent findings that (1) the POSA would not derive the claimed lipid ranges through routine optimization, *'069 Decision*, 18 F.4th at 1376-77; *'069 FWD*, 2020 WL 4237232, at *13; and (2) the prior art did not teach a phospholipid range, *'069 Decision*, 18 F.4th at 1374-75; *'069 FWD*, 2020 WL 4237232, at *12. And these findings were essential to the decisions, as the prior art's failure to teach the phospholipid range or support routine optimization to arrive at the claimed lipid ranges explicitly was held sufficient to foreclose obviousness. *'069 Decision*, 18 F.4th at 1369; *'069 FWD*, 2020 WL 4237232, at *11.

d. Moderna Was Adequately Represented in the Previous Action

Moderna was represented by sophisticated counsel in the prior proceedings, *Jean Alexander*, 458 F.3d at 249; *'069 Decision*, 18 F.4th at 1367 (WilmerHale); *'069 FWD*, 2020 WL 4237232 (Irell & Manella), and had a full opportunity to litigate obviousness before the PTAB and Federal Circuit, *see PureWick*, 2023 WL 2734779, at *10. This element is plainly satisfied.

e. Summary Judgment of Nonobviousness Is Proper

Issue preclusion thus applies to foreclose Moderna from relitigating the PTAB and Federal Circuit's nonobviousness judgment based on its determinations that (1) "routine optimization" would not yield the claimed ranges due to "unpredictable interactivity" of the four lipid components, *'069 Decision*, 18 F.4th at 1376-77, and (2) the prior art does not disclose a phospholipid range, *id.* at 1374-75. *See PureWick*, 2023 WL 2734779, at *5; *Centripetal Networks, LLC v. Palo Alto Networks, Inc.*, 2024 WL 219124, at *7 (E.D. Va. Jan. 9, 2024);

Plaintiffs' Mot. to Exclude at 2-12. As described above, Moderna has not advanced an obviousness argument distinct from what the Federal Circuit already rejected; at most, it raises "different prior art," which is insufficient to avoid summary judgment based on issue preclusion. *Sprint*, 2021 WL 982726, at *9. Indeed, Dr. Anderson invokes "routine optimization" or similar terms a dozen times in his reports, *e.g.*, Ex. 4 (Anderson) ¶¶ 599, 619, 722-723, 823, 830, 834, 929, 948, 967-1006; it is integral to his obviousness theory and relied upon in *each of* his obviousness grounds for *every* asserted claim, *id.* Because obviousness has already been decided adversely to Moderna, the Court should grant summary judgment of nonobviousness.

B. The Court Should Grant Summary Judgment of Enablement

Moderna also asserts that all asserted claims are not enabled. Its evidence, even if taken as true, is legally insufficient to create a triable issue, and summary judgment is therefore proper.

Enablement is a question of law. *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013). The enablement "requirement is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Id.* "Because [courts] must presume a patent enabled, the challenger bears the burden, throughout the litigation, of proving lack of enablement by clear and convincing evidence." *Id.* at 1337. Critically for present purposes, to satisfy that burden, the challenger must "show by way of testimony or documentary evidence the amount of experimentation needed." *Id.* at 1339. Summary judgment is proper where a challenger "fail[s] to meet its burden of proof" because there is "insufficient evidence to demonstrate that others would have been unable to practice the claimed invention without undue experimentation. The fact that *some* experimentation may be necessary to produce the invention does not render the [patent] invalid for lack of enablement." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1337-38 (Fed. Cir. 2006) (emphasis in original). Here, Moderna plainly cannot succeed on enablement as a matter of law.

1. Lipid Composition Patents

Moderna's argument that the claims of the Lipid Composition Patents are not enabled fails for two reasons. First, as explained below and in Plaintiffs' motion to strike, Moderna's experts' non-enablement opinions improperly assume that the claims require functional properties (like efficacy) and argue non-enablement based on those unclaimed properties. Second, Moderna's experts did not advance the requisite specific evidence that practicing the claims would have required undue experimentation, including any example of a claimed particle that the skilled artisan would not have been able to make. Each failure independently merits summary judgment.

a. Moderna Relies on Unrecited Functional Limitations

"Section 112 requires enablement of 'only the claimed invention,' not matter outside the claims." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020). Enablement turns on the experimentation required to make the particles "as claimed." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956-57 (Fed. Cir. 1983). Moderna's enablement arguments flout this rule, asserting that a POSA would have been unable to achieve functional properties, like potency and stability, that the claims never recite. The claims recite "a nucleic acid-lipid particle comprising" nucleic acid and four lipids with indicated ratios. *E.g.*,'435 patent, claim 7. They do not recite, and thus do not require, the particles to possess any functional properties.

Moderna adduced no evidence addressing the POSA's ability to practice the invention "as claimed." Moderna's lead enablement expert, Dr. Prud'homme, asserts that a POSA could not have practiced various limitations to their full scope in the claims, including "___ mol %," "a nucleic acid"/"mRNA," and (in one claim) *in vivo* administration, and thus the claims are not enabled. *E.g.* Ex 7 (Prud'homme) ¶ 24. Critically, however, he nowhere opines that, with the patents in hand, the POSA could not easily have practiced the claims as recited, *i.e.*, made an LNP with the recited molar ratios, or with mRNA inside of it, or administered it *in vivo*. He instead

opines that the claimed particles must exhibit various unclaimed properties, like potency or stability, and the patents do not enable *those* unrecited properties. For example, he contends that, "to determine whether a given formulation can achieve this higher level of potency, a POSA would be required to undergo undue experimentation." Ex 7 (Prud'homme) ¶ 265. He cites to Plaintiffs' IPR statements about the unpredictability of the "properties of nucleic acid-lipid particles" (which are relevant to motivation, despite being unclaimed, *see Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1377 (Fed. Cir. 2021)). Ex 7 (Prud'homme) ¶ 252. And he incorporates his opinions about Plaintiffs' experiments to improve mRNA encapsulation—which (in addition to being a flawed analysis, *infra* Section IV.B.2.a) is a feature not recited in the claims of the Lipid Composition Patents—to "illustrate the undue level of experimentation" required, Ex. 7 (Prud'homme) ¶ 289. Dr. Prud'homme confirmed under oath that these unclaimed elements were the basis of his non-enablement opinion. *E.g.*, Ex. 10 (Prud'homme Tr.) at 287:22-291:8 (agreeing that it would require "undue experimentation to practice the claims" of an exemplary Lipid Composition Patent because, in his view, the claims require at least "[t]herapeutic [*sic*], effectiveness, stability over time under freeze/thaw or some conditions").

As explained in the accompanying motion to exclude, Dr. Prud'homme commits the "cardinal sin" of reading unclaimed properties "from the written description into the claims." Ex 7 (Prud'homme) ¶ 251; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) (en banc). The Court did not construe the claims to require unclaimed properties, whether discussed in the specification as advantages of the invention or otherwise, and Moderna never requested it do so. Dr. Anderson, another Moderna expert, agrees that the claims do not include the very unclaimed properties on which Dr. Prud'homme relies. Ex 6 (Anderson Reply) ¶¶ 194, 213. And during the '435 patent IPR, the PTAB construed the claims *not* to require functional properties—at

Moderna's urging. *'435 FWD*, 2019 Pat. App. LEXIS 13612, at *10-13; Ex 29 (Moderna '435 IPR Reply) at 3-5 (Moderna opposing "interject[ion] of additional limitations into the claims," such as stability).

Dr. Prud'homme nonetheless attempts to rationalize his claim interpretation by citing descriptions in the specification of the advantages of the inventions, Ex 7 (Prud'homme) ¶ 251, but claims need not include all "advantages or features described as significant or important." *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004). Dr. Prud'homme also cites various statements related to "unexpected properties." Ex 7 (Prud'homme) ¶ 324; Ex 9 (Prud'homme Reply) ¶ 193. However, arguments of unexpected properties do not get grafted onto claims, for purposes of enablement or otherwise. *In re Merch.*, 575 F.2d 865, 868 (C.C.P.A. 1978) ("We are aware of no law requiring that unexpected results relied upon for patentability be recited in the claims."); *Invista N. Am. S.A.R.L. v. M & G USA Corp.*, 35 F. Supp. 3d 583, 599 n.12 (D. Del. 2014) (criticizing expert who "conflated the 'unexpected results,' . . . and 'undue experimentation' as it applies to enablement, which is based on the invention as claimed").

Courts routinely reject enablement arguments like Moderna's that focus on properties like "safety and efficacy [that] are not recited in the claims." *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1370-71 (Fed. Cir. 2023); *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014) ("[A] patent does not need to guarantee that the invention works for a claim to be enabled."); *Janssen Pharm., Inc. v. Tolmar, Inc.*, 718 F. Supp. 3d 394, 417 (D. Del. 2024) (claims "say nothing about drug concentrations or a therapeutic window"). Dr. Prud'homme's opinions fall squarely within this precedent and cannot create a triable fact issue. *Monsanto*, 459 F.3d at 1334 ("[O]nly those disputes over facts that might affect the outcome of the lawsuit under the governing substantive law will preclude summary judgment.").

b. Moderna Lacks Evidence Sufficient to Avoid Summary Judgment of Enablement on the Lipid Composition Patents

In addition to its reliance on unclaimed properties, Moderna failed to adduce *any* evidence that *any* scientist ever has been unable to practice the claims, much less that it required undue experimentation to do so. That failure separately dooms Moderna's defense as a matter of law.

It is well established that the undue experimentation test "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine." *Johns Hopkins Univ. v. CellPro*, 152 F.3d 1342, 1360 (Fed. Cir. 1998); *Cephalon*, 707 F.3d at 1338 ("[E]xtensive experimentation" is permissible "where the experiments involve repetition of known or commonly used techniques."). "[T]rial and error" can be required to practice an enabled claim, if it would not be "unduly laborious or beyond the reach of one of ordinary skill," *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (affirming enablement JMOL). The Supreme Court recently reaffirmed longstanding precedent that a specification is not "inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 611 (2023). "[A] specification may call for a reasonable amount of experimentation to make and use a patented invention" and still satisfy enablement. *Id.* at 612. Claims are not enabled where a patent requires the POSA to engage in "elaborate" or "painstaking experimentation" to practice them. *Id*. at 610, 614; *Johns Hopkins*, 152 F.3d at 1360.

Because experimentation is permissible, a challenger must specifically "show by way of testimony or documentary evidence the amount of experimentation needed" to practice the claims to establish non-enablement. *Cephalon*, 707 F.3d at 1339. Challengers must advance "clear and convincing evidence" that guidance purportedly omitted from the specification "was necessary to practice the claimed invention without undue experimentation." *Koito Mfg.,* 381 F.3d at 1155 (affirming JMOL of enablement); *McRO*, 959 F.3d at 1102 (a "patent need not teach . . . what is

well known in the art"). Critically, "*ipse dixit* statements . . . cannot be enough to constitute clear and convincing evidence" of non-enablement. *Cephalon*, 707 F.3d at 1338. Nor are "unsubstantiated conclusory statement[s]" about parameters that "*may* affect" various claimed properties and the experimentation required to assess them sufficient. *Alcon Rsch.*, 745 F.3d at 1189; *Johns Hopkins*, 152 F.3d at 1360 (affirming summary judgment because statements that a method is "difficult" are insufficient to establish non-enablement); *InterDigital Commc'ns, Inc. v. ZTE Corp.*, 2014 WL 4272726, at *3 (D. Del. Aug. 28, 2014) (summary judgment of enablement because defendant failed to present "evidence concerning the amount of experimentation needed").

Ipse dixit and unsubstantiated statements are all Moderna's experts offer. Fatally, neither Dr. Prud'homme nor Dr. Meulien (another expert who briefly opines on enablement) describes—with any specificity—what experimentation was required to make the claimed particles, let alone provides evidence that such experimentation was "undue." Ex 7 (Prud'homme) ¶¶ 252, 255, 259, 263, 265, 287-290, 327-331; Ex 8 (Meulien) ¶¶ 157-159. Instead, these experts offer precisely the type of conclusory assertions that courts routinely find insufficient—even the section of Dr. Prud'homme's report entitled "Quantity of Experimentation Needed" offers nothing more than conclusory statements. *E.g.*, Ex 7 (Prud'homme) ¶¶ 255-265; *see also* Ex 10 (Prud'homme Tr.) 289:21-291:8 (explaining his undue experimentation opinion as "[Plaintiffs'] worked hard to get compositions which were useful for them . . . but they still had to do more and more experiments to get the desired results"). Dr. Prud'homme's opinions relying on unclaimed properties, already improper, are likewise conclusory and inadequate under the governing law, as he fails to explain the experimentation supposedly needed to achieve the particles' unclaimed features. *See* Ex 7 (Prud'homme) ¶ 265; Ex 10 (Prud'homme Tr.) 289:21-291:8; *Alcon*, 745 F.3d at 1189.

Moderna also cannot avoid summary judgment based on Dr. Prud'homme's contention that

undue experimentation was required to *measure* the lipid composition of a "particle" (to which the claims are directed). Ex 7 (Prud'homme) ¶ 256. First, no such measurement is required to practice the claims, which involves making particles rather than measuring them. *Therasense, Inc. v. Becton, Dickinson & Co.*, 560 F. Supp. 2d 835, 879 (N.D. Cal. 2008) ("[T]he test for enablement is . . . not whether one of ordinary skill of the art could easily assess whether" the device infringes.); *see also Eli Lilly & Co. v. Actavis*, 435 F. Appx. 917, 925 (Fed. Cir. 2011) ("§ 112 requires nothing more than objective enablement"). Second, even were such a measurement relevant to enablement, Dr. Prud'homme concedes that the test a POSA would have used to measure lipid compositions (HPLC) is "standard" (*i.e.*, routine). Ex 7 (Prud'homme) ¶ 258; Ex 5 (Murthy) ¶¶ 106, 1214-1216. HPLC provides "aggregate" measurements—that is, it measures the total lipid concentrations of all the particles in a sample. Ex 5 (Murthy) ¶ 1214. Plaintiffs' expert explained that such "an aggregate lipid composition measurement of a sample *is* informative about the composition of individual lipid particles." *Id.* ¶ 1217. Rather than provide evidence disputing this testimony, Dr. Prud'homme agreed that some particles "certainly may" have the lipid composition measured by HPLC. Ex 10 (Prud'homme Tr.) 37:4-14. As such, to the extent enablement requires assessing lipid particles (it does not), Moderna cannot meet its burden to prove that an admittedly routine measurement technique does not yield data reflecting the lipid composition of a "particle."

Nor can Moderna avoid summary judgment based on its expert's flawed attempt to show inoperative embodiments. At the outset, that a claim includes some inoperative embodiments within its scope does not render it non-enabled. "It is not a function of the claims to specifically exclude . . . possible inoperative substances." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Instead, "the number of inoperative combinations" must be "significant, and in effect force[] one of ordinary skill in the art to experiment unduly."

Id. at 1576-77. Moderna's evidence, even if credited, does not show a single inoperative embodiment, much less a "significant" number of them. *E.g.*, Ex 9 (Prud'homme Reply) ¶¶ 162-166; Ex 8 (Meulien) ¶¶ 157-158. Though Dr. Prud'homme and Dr. Meulien speculate that a POSA may have had difficulty making particles with "chromosomal DNA," Ex 11 (Meulien Reply) ¶ 43; Ex 9 (Prud'homme Reply) ¶ 209, the article they cite for that single alleged inoperative embodiment does not use the claimed lipid components and is thus not a "claimed combination[]." *Atlas Powder*, 750 F.2d at 1576. Regardless, they again offer no evidence about the amount or type of experimentation needed to make the claimed particles with that single kind of nucleic acid, or that it represents a "significant" number of inoperative combinations. The gaps in Moderna's proof are fatal to its enablement challenge, and summary judgment is proper.

2. '651 Patent

Moderna's enablement challenge to the '651 patent is likewise deficient. That patent claims lipid vesicle formulations wherein recited percentages of the mRNA in the formulation is fully encapsulated in the lipid vesicles. Dr. Prud'homme asserts that a POSA could not have practiced various limitations to their full scope in the claims, including "fully encapsulated," "at least 70% [or 80% or 90%] . . . fully encapsulated," and "mRNA," and thus the claims are not enabled. *E.g.* Ex 7 (Prud'homme) ¶ 20. Moderna's experts conflate arguments about the *quantity* of experimentation that may be needed to practice a claim with the required specific showing that such experimentation is *undue*. In doing so, Moderna's experts again improperly rely on unclaimed properties, assume that all modes of making an invention must be enabled, and ignore affirmative evidence of researchers, including Moderna's own scientists, practicing across the scope of the '651 patent *without* undue experimentation. As such, summary judgment is proper.

a. Moderna's Experts Failed to Define or Identify Undue Experimentation as is Required for Non-Enablement

As above, Moderna's defense presents "insufficient evidence to demonstrate that others would have been unable to practice the claimed invention without undue experimentation." *Monsanto*, 459 F.3d at 1338. Moderna's evidence amounts to "[u]nsubstantiated statements indicating that experimentation would be difficult and complicated," which "are not sufficient" to meet its burden of proof. *Cephalon,* 707 F.3d at 1339 (reversing non-enablement judgment).

Dr. Prud'homme opines that because the '651 patent claims are not limited to specific (a) classes of the claimed lipids, (b) molar ratios, or (c) vesicle structures, they "are so broad that Plaintiffs cannot possibly . . . have enabled it all." Ex 7 (Prud'homme) ¶¶ 149-154, 158, 161-169 (A POSA "would have to go through an exceedingly extensive formulation campaign to identify formulations that would fall within the claims, varying both process and composition variable. The amount of work required would fall well within 'undue' experimentation."), 181, 186, 199-200. Dr. Meulien similarly opines, without evidence, that achieving "the encapsulation percentages when formulating with one particular mRNA [] does not evidence that [one] would also be able to achieve those encapsulation percentages with larger [mRNA]." Ex 11 (Meulien Reply) ¶ 32.

These are precisely the type of non-specific opinions the Federal Circuit repeatedly has deemed insufficient as a matter of law to show non-enablement. In *Alcon*, the court reversed an invalidity judgment due to the insufficiency of the enablement allegations, as defendants "adduced no evidence [] that changing any of the variables or [v]arious parameters . . . would render Alcon's claimed invention inoperable, nor was there any evidence that experimenting with those variables was required for an ordinarily skilled artisan to be capable of" practicing the claims. 745 F.3d at 1189. So too here, as Moderna provides no evidence that experimentation with the parameters—including classes of lipids, molar ratios, vesicles, or mRNA—is required to practice the claims, or that such experimentation would be undue. *Koito Mfg.*, 381 F.3d at 1155-56 (granting JMOL

where challengers failed to show that the omitted production details were (a) required to practice the claims and (b) would necessarily elicit undue experimentation). Merely asserting "that experimentation would be 'difficult' and 'complicated'"—precisely the arguments Moderna's experts advance—is not enough to create a factual issue as to enablement. *Cephalon*, 707 F.3d at 1339; *Johns Hopkins*, 152 F.3d at 1360 (affirming summary judgment, holding statement that a method is "difficult" is insufficient to establish non-enablement); *Alcon*, 745 F.3d at 1189 (statements such as "when you have a lot of variables on top of one another, the experimentation gets out of control" are "unsubstantiated," "conclusory," and "not sufficient" as a matter of law).

To support their enablement positions, Moderna's experts point principally to formulation studies that Plaintiffs performed in 2013 and 2014 and assert that Plaintiffs "had to undergo an extensive campaign—performing an iterative trial-and-error process in varying both elements of the composition as well as the process—to achieve the claimed level of encapsulation." Ex 7 (Prud'homme) ¶ 183; Ex 8 (Meulien) ¶¶ 145, 158; Ex 10 (Prud'homme Tr.) 274:14-276:4. Even if taken as true for purposes of this motion, those assertions cannot create a fact question for the jury. As noted above, extensive trial and error does not show non-enablement, particularly where the experimentation involved "commonly used techniques." *Cephalon.* 707 F.3d at 1338. Instead, non-enablement requires a showing that the "trial and error . . . would be unduly laborious or beyond the reach of one of ordinary skill in the art." *Koito Mfg.* 381 F.3d at 1155 (affirming JMOL of enablement). Moderna cannot show a genuine issue of material fact when its experts nowhere provide that opinion in any non-conclusory way—or provide evidence that the supposed "trial and error" required to practice the claims was "elaborate," "painstaking," and "beyond the reach of one of ordinary skill in the art." *Koito Mfg.* 381 F.3d at 1155; *Amgen*, 598 U.S. at 610, 614.

What is more, it is well established that "[a] party who wishes to prove that the claims of a

patent are not enabled by means of a failed attempt to make the disclosed invention must show that the patent's disclosure was followed." *Johns Hopkins*, 152 F.3d at 1360. Neither of Moderna's experts attempt such a showing for the 2013 and 2014 work—giving a jury no basis to conclude those experiments support non-enablement. Indeed, Dr. Prud'homme suggests that the patent's disclosures were *not* followed in those studies. Ex 9 (Prud'homme Reply) ¶¶ 105 ("[N]o indication that Plaintiffs' scientists . . . strictly followed [the '651 patent's] parameters."), 107.

The evidence the law requires Moderna to develop—that the experimentation required to practice the claim is "elaborate" or "painstaking"—is utterly lacking. Indeed, rather than cite experimental records of the underlying 2013 and 2014 experiments such as lab notebooks, Drs. Prud'homme and Meulien largely base their opinions on a summary report about Plaintiffs' efforts "to reduce particle size and improve encapsulation"—*see* Ex 7 (Prud'homme) ¶¶ 116, 204; Ex 9 (Prud'homme Reply) ¶¶ 121, 175; Ex 8 (Meulien) ¶¶ 145, 158. But reduced particle size is not a claim limitation and is thus legally irrelevant to enablement. *McRO*, 959 F.3d at 1100; *supra* Section IV.B.1.a. Moreover, Moderna's experts do not contest Dr. Murthy's account of the experimental records that, after just a handful of experiments in 2013-2014, Plaintiffs achieved the claimed percentages of encapsulation of mRNA, or that the parameter adjustments that resulted in high encapsulation were taught by the patent and otherwise routine. Ex 5 (Murthy) ¶¶ 682-686, 717-718 (citing Plaintiffs' lab notebooks, PowerPoints, depositions, and emails); Ex 10 (Prud'homme Tr.) 274:14-275:2 (declining to opine that the few parameter changes in the experiments were undue, instead stating that two months is "a whole lot of experimentation"). Indeed, Moderna's experts do not identify the requisite particular embodiments, such as a specific combination of lipids, that could not be used to achieve the claimed percentages of full encapsulation using the disclosures of the patent and routine experimentation. *McRO*, 959 F.3d at

1101 (requiring "concrete identification of matter that is not enabled but is or may be within the claim scope"). Despite Plaintiffs' repeated cautioning of their evidentiary shortcomings, Moderna's experts provided no evidence that Plaintiffs' 2013-2014 studies required undue experimentation and thereby failed to meet the standard required. *Cephalon,* 707 F.3d at 1339.

But Moderna's argument is far more defective than the assertions rejected as a matter of law in *Johns Hopkins*, *Cephalon*, and *Koito*, as Moderna's experts either ignore or fail to rebut the overwhelming evidence demonstrating that numerous scientists—from Plaintiffs, Moderna, and elsewhere—had no difficulty practicing the claimed invention based on the patent's guidance.

Plaintiffs. In 2009—years before the 2013-2014 work Moderna's experts cite— Plaintiffs' inexperienced scientist practiced the claims (including the claimed levels of encapsulated mRNA), *in a single day*, by making adjustments taught by the patent. Ex 5 (Murthy) ¶¶ 680-681, 718-719. Courts routinely look to such evidence of successfully practicing the claims in assessing enablement, including in the summary judgment context. *E.g.*, *Johns Hopkins*, 152 F.3d at 1361 (holding successful production of some claimed antibodies "suggests that the disclosure . . . in the patent was sufficient to enable those of ordinary skill to produce a host of [the claimed] antibodies"). As the Supreme Court aptly observed, "when the question is whether a thing can be done or not, it is always easy to find persons ready to show how not to do it. *If one succeeds, that is enough, no matter how many others fail.*" *Telephone Cases*, 126 U.S. 1, 536 (1888).

Moderna's experts largely ignored this evidence of Plaintiffs' successful formulation work and did not explain how their conclusory undue experimentation opinion can survive it (it cannot). Their sole criticism was that this work used a buffer (EDTA) not listed in the patent. Ex 9 (Prud'homme Reply) ¶ 106. This critique cannot create a factual dispute to avoid summary judgment, as the law required Moderna to "provide evidence [] that the production details omitted

[from the patent] would have made one of ordinary skill in the art unable to practice the claimed invention without undue experimentation." *Koito*, 381 F.3d at 1155. Dr. Prud'homme did not even attempt to make such a showing. To the contrary, he specifically admitted that buffers other than EDTA, including a buffer featured in the patent, "can be used" to successfully encapsulate mRNA. Ex 10 (Prud'homme Tr.) 270:6-18. Moderna's failure to provide legally sufficient opinions refuting that Plaintiffs' scientist used the patent's teachings and easily practiced the claims, precludes Moderna from demonstrating that undue experimentation was required.

Moderna. Moreover, Moderna *itself* successfully used the techniques described in the '651 patent to achieve the claimed levels of encapsulation without undue experimentation, via experiments carried out by its first in-house formulator, Dr. Kristy Wood. Ex 5 (Murthy) ¶¶ 698, 726. Moderna's experts do not dispute this evidence. They instead argue that "there is no indication that any [Moderna] scientist tried to follow the methods disclosed in the '651 patent." Ex 9 (Prud'homme Reply) ¶ 117. That is irrelevant (and also incorrect, Ex 5 Murthy ¶ 698). Whether Dr. Wood subjectively intended to follow the patent's methods is legally inapt, as "§ 112 requires nothing more than objective enablement"—the ability to practice the invention without undue experimentation, exactly what Dr. Wood's work shows. *Eli Lilly*, 435 F. Appx. at 925. Dr. Prud'homme identifies no aspect of Dr. Wood's work that differed from the patent's teachings—indeed, he conceded that he had not reviewed her experiments and had "no opinion on what she did or the experimentation that it required." Ex 10 (Prud'homme Tr.) 282:19-283:5 ("Q. Do you have any opinion that what Dr. Wood did in her experimentation to make mRNA LNPs in 2012 to 2013 time frame for Moderna was undue experimentation? A. I don't believe I reviewed all of her work."). Moderna cannot prove that it would have required undue experimentation to practice the claims when its experts do not dispute that *Moderna itself* was easily able to do so.

Other Researchers. Consistent with the internal work by Plaintiffs and Moderna, it is also uncontested that the literature reflects that many researchers used the methods in the patents and had no apparent difficulty achieving the claimed invention without undue experimentation. Ex 5 (Murthy)¶¶ 701, 709, 712, 727-728, 1416. Though this unrebutted evidence is not required to foreclose non-enablement, it further supports summary judgment, as it frustrates any attempt by Moderna to advance the requisite "evidence to demonstrate that others would have been unable to practice the claimed invention without undue experimentation." *Monsanto*, 459 F.3d at 1338.

b. Moderna's Additional Arguments Do Not Create a Factual Dispute that Avoids Summary Judgment

Lacking the legally mandated concrete, experimental examples of undue experimentation to avoid summary judgment, *McRO*, 959 F.3d at 1101 —and in the face of the overwhelming affirmative evidence that the patent *does* enable the claims—Moderna's experts seek to fill the gap with a hodgepodge of opinions that are legally improper or irrelevant to the enablement inquiry.

First, Moderna's experts again rely on unrecited properties. Ex 7 (Prud'homme) 151 n.5 ("The laundry list of ionizable lipids [from the patent] does not provide guidance for a POSA on which lipids to choose, and how ***transfection efficiency, toxicity, LNP stability, and other effects*** would depend on the lipid chosen. For this additional reason, all of the Asserted Claims are not enabled."). None of these properties is required to practice the claims. As explained in the motion to exclude filed herewith, unclaimed properties are irrelevant to enablement. *McRO*, 959 F.3d at 1100; *United Therapeutics*, 74 F.4th at 1369-70; *supra* IV.B.1.a. Even if, contrary to established precedent, unclaimed features could be read into the claims, Moderna lacks the required showing of undue experimentation, as with its other enablement arguments. *Koito*, 381 F.3d at 1155.

Second, Moderna's experts assert non-enablement because a skilled artisan could not have used alternatives to the disclosed method, such as *prior art methods*, to achieve the claimed full

encapsulation levels. Ex 7 (Prud'homme) ¶¶ 182, 184, 188-189. That argument traduces the black-letter rule that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins*, 152 F.3d at 1361. The claims are directed to compositions, not methods of making compositions. The disclosure of a single method (mode) that achieves the invention without undue experimentation suffices as a matter of law, and whether undue experimentation would be required to practice the claims with other modes is "legally irrelevant." *Id*. Dr. Prud'homme's purported evidence related to inferior prior-art methods of making lipid particles or later-developed methods—which differ from the methods set forth in the patent that *can* be used successfully—is simply irrelevant. *Johns Hopkins*, 152 F.3d at 1361 (finding purportedly non-enabled method "legally irrelevant" because the challenger must "show[] that *all* of the disclosed alternative modes are insufficient to enable the claims").

Third, Dr. Prud'homme opines that the POSA would not know how to measure "partial encapsulation." Ex 7 (Prud'homme) ¶¶ 170-171. That opinion is irrelevant because the claims are not directed to, and do not require measurement of, partially encapsulated mRNA. Ex 5 (Murthy) ¶ 519. Enablement addresses whether the POSA "could practice the invention," *Cephalon*, 707 F.3d 1336, not whether the POSA can measure full encapsulation and assess infringement. *Therasense,* 60 F. Supp. 2d at 879; *Eli Lilly*, 435 F. Appx. at 925. And enablement certainly does not require measuring *partially* encapsulated mRNA, which is not in the required percentage limitation of the claim and which Dr. Prud'homme concedes he has no reason to believe exists in the formulations at issue. Ex 10 (Prud'homme Tr.) 189:14-191:21 ("I don't believe anyone has seen" mRNA that is part in and part out of an LNP, "I have never seen any Moderna data indicating that" Moderna's mRNA pokes through the LNP).

Regardless, it is uncontested that there existed standard methods at the priority date for

measuring encapsulation, such as "dye-exclusion" assays. Ex 5 (Murthy) ¶ 574; Ex 9 (Prud'homme Reply) ¶ 92. It is likewise uncontested that this testing is "relatively quick, cheap, and easy," *id.* ¶ 674, a far cry from undue experimentation. Dr. Prud'homme's sole "evidence" of undue experimentation is that Moderna "pour[ed] time and resources" into seeing if one could distinguish between fully and partially encapsulated mRNA, Ex 7 (Prud'homme) ¶ 171, though he does not provide any details regarding Moderna's efforts (*e.g.*, length of time, amount of money, types of techniques, or experiments). Along with their irrelevance, these are precisely the type of "*ipse dixit*" statements that "cannot be enough to constitute clear and convincing evidence" of non-enablement, and, regardless, Dr. Prud'homme fails to show that the purportedly "considerable amount of experimentation" referenced is undue. *Cephalon*, 707 F.3d at 1338-39; *supra* Section IV.B.2.a. As with its other arguments, Moderna lacks the legally mandated evidence of undue experimentation. Summary judgment is therefore proper.

C. The Court Should Grant Summary Judgment of No Derivation

Moderna contends that *it*, not Plaintiffs, first conceived the invention. Ex 7 (Prud'homme) ¶¶ 333-334. Astoundingly, Moderna relies on a patent application it filed in 2012—a decade *after* the '651 patent's priority application and three years *after* Moderna concedes Plaintiffs practiced the invention. Moderna's derivation argument fails as a matter of law.

"A claim that a patentee derived an invention addresses originality—who invented the subject matter of the count?" *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993). To prove derivation, "the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee by clear and convincing evidence." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003). "The communication must be sufficient to enable one of ordinary skill in the art to make the patented invention." *Id.* Such communication also must encompass all limitations of the claimed invention. *See*

Cumberland Pharms. Inc. v. Mylan Institutional LLC, 846 F.3d 1213, 1218 (Fed. Cir. 2017). Moderna comes nowhere close to creating a material factual dispute under these standards.

Unusually, Moderna does not assert that it conceived the invention before the '651 patent's priority application was filed in 2002. Moderna did not exist at that time. Instead, Moderna asserts that the 2002 application did not show invention or enablement of the claimed lipid formulations with mRNA. Thus, Moderna argues, when it practiced the same invention and published its own patent application a decade later, it was somehow first. Ex 7 (Prud'homme) ¶ 336. This is nothing more than a meritless section 112 defense masquerading as a derivation argument. *See supra* Section IV.B.2. But even if Moderna properly could smuggle a section 112 defense under the guise of derivation, it still fails as a matter of law for at least two independent reasons.

First, Moderna's expert conceded that Plaintiffs practiced the claimed invention in 2009—years before Moderna allegedly conceived the invention and communicated it to Plaintiffs. Plaintiffs' Mr. Reid undisputedly achieved 86-95% full encapsulation of mRNA on November 10, 2009. *Supra* Section IV.B.2.a. Dr. Prud'homme agrees, referencing Mr. Reid's 2009 experiment and admitting that "Plaintiffs . . . were able to encapsulate mRNA in LNPs years after 2002." Ex 9 (Prud'homme Reply) ¶ 140 (citing Ex 5 (Murthy) ¶¶ 486-490). Dr. Prud'homme's response that the 2009 work is "not probative of whether the claims" were "described and enabled by the priority applications as of 2002," Ex 9 (Prud'homme Reply) ¶ 140, is legally insufficient under section 112, *supra* Section IV.B.2, and more importantly here, irrelevant to derivation. It is logically and legally impossible that Plaintiffs derived from Moderna an invention that Moderna admits Plaintiffs practiced first. *Cumberland Pharms.*, 846 F.3d at 1218-19.

Second, even if Moderna *could* rely on its later 2012 application, it adduced no evidence that the application disclosed all limitations of the claims, as required to prove derivation. *See id.*

Dr. Prud'homme never propounded such an opinion. He instead opined that Moderna's 2012 application discloses each limitation *only insofar as the '651 patent's priority application adequately describes and enables the claimed invention*. *See* Ex 10 (Prud'homme Tr.) at 323:8-324:17 (whether Moderna's application discloses the "fully encapsulated" limitation "is a little more complex" and premised on the '651 patent adequately describing the claimed invention), 325:17-326:6 ("I think that the word 'fully' is not described and [Moderna's 2012 application] doesn't address that"), 326:7-327:8 (Moderna's 2012 application "doesn't address the issues of enablement or written description" that Dr. Prud'homme asserts exist for the '651 patent and its priority application); Ex 7 (Prud'homme) ¶ 343. But the entire premise of Dr. Prud'homme's derivation argument is that Plaintiffs' '651 patent and its earlier priority application do *not* adequately describe and enable the claimed invention. Ex 7 (Prud'homme) ¶¶ 336-337. Dr. Prud'homme cannot have it both ways. Since Dr. Prud'homme admitted that the disclosure of Moderna's 2012 patent application and the '651 patent's 2002 priority application rise and fall together, Moderna cannot establish derivation. One of two things must be true: either (1) Plaintiffs are correct that the '651 priority application describes and enables the claimed invention, in which case Moderna's derivation defense fails because the '651 priority application predated Moderna's application by a decade, or (2) the '651 priority application does not describe and enable the claimed invention, in which case neither does Moderna's 2012 patent application. Either way, Moderna's derivation defense cannot succeed as a matter of law.[4]

V. CONCLUSION

The Court should enter summary judgment for Plaintiffs of (a) Nonobviousness of the Lipid Composition Patents, (b) Enablement for all Asserted Patents, and (c) No Derivation.

[4] The '651 priority application does adequately describe and enable the claimed invention. *See, e.g.*, *supra* Section IV.B.2; Ex 5 (Murthy) ¶ 580.

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CERTIFICATE OF SERVICE

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